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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,298	08/08/2001	Vincent Bryan	46739/262600	3319

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EXAMINER

PRIDDY, MICHAEL B

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,298

Applicant(s)

BRYAN ET AL.

Examiner

Michael B Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 21-29, 34-44, 86-92, 112 and 113 is/are allowed.
- 6) ☐ Claim(s) 1-3, 8, 10-15, 30-33, 45-68, 70-74, 77-84, 93-105, 111 and 114-119 is/are rejected.
- 7) ☐ Claim(s) 4-7, 9, 16-20, 69, 75, 76, 85 and 106-110 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

The drawings are objected to because in Fig. 6, reference numeral 88 indicates the sheath 70 while it should indicate the radial stop equivalent to 86 as properly illustrated in Fig. 8B. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(f). A proper abstract should be a brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims.

Claim Objections

Claim 1 is objected to because of the following informalities: in line 12, "coplements" should be --compliments--. Appropriate correction is required.

Claim 7 is objected to because of the following informalities: in line 2, ", and" should be deleted. Appropriate correction is required.

Claim 10 is objected to because of the following informalities: in line 2, "an" should be --a--. Appropriate correction is required.

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Claim 21 is objected to because of the following informalities: in line 13, --a-- should be inserted before "motion" and in line 14, --of the inner surface-- should be inserted after "motion limiting device". Appropriate correction is required.

Claim 73 is objected to because of the following informalities: in line 2, "on" should be --one--. Appropriate correction is required.

Claim 113 is objected to because of the following informalities: in line 1, "coat" should be --coating--. Appropriate correction is required.

Claim 118 is objected to because of the following informalities: in line 1, "14" should be --114--. Appropriate correction is required.

Claim Rejections - 35 USC § 112 1st

Claim 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 13 requires the outer surface of each shell be cooled with a biocompatible porous coating. The disclosure does not appear to set forth the specifics of how or why each shell is cooled with a biocompatible porous coating. It is therefore unclear how to interpret claim 13 in light of the specification.

Claim Rejections - 35 USC § 112 2nd

Claims 8, 30-33, 81 and 114-119 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the central body retainer" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 recites the limitation "the sheath" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 81 includes the limitation "an edge" in line 1. "An edge" has already been recited in line 2 of claim 80 from which 81 depends. It is therefore unclear whether the edge of claim 81 is the same as that of claim 80 or an additional edge.

Claim 114 recites the limitation "the outer surface" in line 4 and "the inner surface" in line 5. There is insufficient antecedent basis for these limitations in the claim.

Claim 119 recites the limitation "the outer and inner surfaces" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Furthermore, there is an implicit lack of antecedent basis for "a, b and c" as recited in line 1 since these terms have not been defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 10-12, 97-100, 111 and 119 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryan et al. (US 5,674,296). Bryan et al. teach a surgical implant 18 suitable for use in a joint between the surfaces of two bones 12 & 14, comprising: two rigid opposing shells 32 & 34, each having an outer surface 52 & 54 adapted to engage the surfaces 112 & 114 of the bones 12 & 14 of a joint in such a way that movement of the shell relative to the bone surface is resisted by friction between the outer surface and the surface of the bone and each having a tab 72 & 74 extending axially way from the central body; an inner surface 62 & 64 that is smoother than the outer surface 52 & 54; and an edge between the outer surface and the inner surface; a deformable, resilient central body 20 disposed between the inner surfaces 62 & 64 of the shells 32 & 34 comprising an outer surface, at least a portion of which has a shape that compliments and articulates with the shape of the inner surface of one or both rigid opposing shells to allow the inner surface of the rigid opposing shell and the outer surface of the central body to move easily with respect to each other within a constrained range of motion, but to resist such movement outside the constrained range of motion; and further comprising a flexible sheath 110 extending between edges of the opposing shells, having an inner surface that, together with the inner surfaces of the rigid shells, defines a cavity containing the central body. Bryan et al. further teach that the central body 20 is comprised of a "relatively stiff annular gasket exterior portion 22 and a relatively supple nuclear central portion 24.

It should be noted that the language "adapted to releasably receive a tool for manipulating, inserting or removing the implant" in lines 1-2 of claim 11 is merely functional and does not explicitly require a tool. It is the belief of the examiner that the elements 72 & 74 are capable of performing the function of receiving a tool.

Claims 45-63 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Büttner-Janz et al. (US 5,401,269). Büttner-Janz et al. teach an implant comprising a central body 3 encapsulated by two shells 1 & 2, said central body 3 having an upper, convex and a lower, convex contact surface 6, wherein an upper shoulder 7 extends around a portion of the perimeter of the upper contact surface 6 and a lower shoulder 7 extends around a portion of the perimeter of the lower contact surface 6. Central body may further include a central axial opening 14 therein. Shells 1 & 2 include surfaces roughened by teeth 5.

Claim 74 is rejected under 35 U.S.C. 102(b) as being anticipated by Ray et al. (US 6,123,465). Ray et al. teach a bone joint implant 20 comprising a central body 22 and a lubricant encapsulated within a structure 24 having at least one opening 36 for the introduction of the lubricant into the structure. Openings 36 are large enough to allow bodily fluids "lubricants" to interact with hydrogel core 22.

Claims 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Buettner-Janz et al. (US 4,759,766). Buettner-Janz et al. teaches an intervertebral disc endoprosthesis comprising a central body positioned between two shells 21 wherein at least one shell includes an inner surface having a central retaining post 19 extending therefrom and adapted to allow rotation of the shells 21 relative to the central body

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wherein the retaining post 19 is substantially centrally located on the inner surface and wherein the inner surface is of a shape that articulates with the shape of at least a portion of the central body.

Claims 80, 83 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (US 5,370,697). Baumgartner teaches an artificial intervertebral disk member comprising a central body 5 positioned between two shells 2 & 3, wherein the shells have edges that include radial stops 16 & 17 extending generally axially from portions thereof and wherein the shells have edges that include tabs 28 extending generally axially from portions thereof. It should be noted that the language "a shoulder" in lines 1-2 of claim 83 does not explicitly require "a shoulder" be present on the central body as this feature has been recited only functionally.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. as applied to claim 2 above, and further in view of DE 3343863. Bryan et al. teach all of the limitations of the present invention except that a liquid lubricant occupies at least a portion of the cavity.

DE 3343863 describes a joint endoprosthesis including a protected space containing the joint cavity 8 which can be filled with a lubricant 10. It would have been obvious to one of ordinary skill in the art at the time of the present invention to have supplied a lubricant in the cavity containing the central body to reduce friction, head and wear.

Claims 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Büttner-Janz et al. in view of Walker (US 4,193,139). Büttner-Janz et al. teach a bone joint implant comprising a central body 3 positioned between two shells 1 & 2 each having an inner surface that contacts the central body. Hence Büttner-Janz et al. teach all of the limitations of the present invention except that the inner surfaces of the shells 1 & 2 are machined or polished.

Walker teaches a prosthetic finger joint 10 comprised of a first stemmed component 12; a second stemmed component 14; a bearing pad 16; a bushing 18; and an axle 19. "Arcuate bearing surface 25 is polished smooth, so as to facilitate the pivoting motion of the first component of the joint in use, and also to reduce unnecessary friction in the movement of the joint, thus reducing wear of pad 16." (lines 56-61 of column 3) It would have been obvious to one of ordinary skill in the art at the time of the present invention to polish the inner surfaces of the shells of the implant of Büttner-Janz et al. so as to improve their wear characteristics when articulating with the central body 3.

Claims 66-68, 70, 71 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Büttner-Janz et al. in view of Ducheyne et al. (US 4,990,163).

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Büttner-Janz et al. teach a central body 3 positioned between two shells 1 & 2 having outer surfaces. Therefore Büttner-Janz et al. teach all of the limitations of the present invention except that the outer surface of at least one of the shells is coated to promote bony ingrowth.

Ducheyne et al. teach a method of depositing calcium phosphate ceramics for bone tissue calcification enhancement. This procedure is used to facilitate bony ingrowth when using cementless fixation of permanent implants. The method, as described in lines 19-30 of column 11 and in the first paragraph of column 12, involves the vacuum sintering of a mixture of hydroxyapatite onto titanium. It would have been obvious to one of ordinary skill in the art at the time of the present invention to provide a coating of hydroxyapatite onto the outer surface of the shells of Büttner-Janz et al. so as to enhance bone ingrowth thereinto. Concerning the limitation of claims 70 and 71 requiring the material be of titanium it would have been obvious to one having ordinary skill in the art at the time the invention was made to use whatever material was deemed appropriate for the particular application, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416

Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner as applied to claim 80 above, and further in view of the following. Baumgartner discloses the claimed invention except that the radial stop extends a distance of less than about 2.5 mm from the edge. It would have been obvious to one having ordinary skill in the art at the time the invention was made to for the stop of

whatever dimensions would have been appropriate for the particular application, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233

Claims 93-96, 101-103 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Buechel et al. (US 5,868,796). Bryan et al. teach a surgical implant 18 comprising an elastomeric central body 20 positioned between two shells 32 & 34. Bryan et al. therefore teach all of the limitations of the present invention except that the central body 20 is impregnated with a surface hardening or lubricity increasing material.

Buechel et al. teach a biologically inert wear resistant surface 26 on the head 18 of a femoral, stem-type prosthesis. The surface is the result of a titanium nitride coating. "The much smoother characteristics of surfaces subjected to wear that are enabled by the harder coating 26 contribute substantially to wear resistance, abrasion resistance and lubricity." It would have been obvious to one of ordinary skill in the art at the time of the present invention to apply titanium nitride to the bearing surface of the central body 20 of Bryan et al. so as to substantially improve its wear resistance.

Claims 104 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Waits (US 5,593,445). Bryan et al. teach a bone joint implant comprising a central body 20 positioned between two shells 32 & 34.

Therefore, Bryan et al. teaches all of the limitations of the present invention except that the central body has a polymer coating thereon.

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Waits teaches a bi-axial prosthetic joint the articulating surfaces of which may be coated with polyurethane or other biocompatible polymeric resins to further reduce friction (col. 11, lines 20-23). It would have been obvious to one of ordinary skill in the art at the time of the present invention to coat the outer surface of the central body of Bryan et al. with polyurethane so as to reduce the friction between the central body and the shells 32 & 34.

Allowable Subject Matter

Claims 21-29, 34-44 and 86-92 are allowed.

Claims 4-7, 9, 16-20, 69, 75, 76, 85, 106-110, 112 and 113 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 30-33, 114-118 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claim 8 and 81 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy

Michael B. Priddy
February 9, 2003

Kevin Shaver
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